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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/787,030	02/25/2004	Thomas Preston Kennedy	046428/275157	3913

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EXAMINER

ANDERSON, JAMES D

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/787,030	<b>Applicant(s)</b> KENNEDY, THOMAS PRESTON	
	<b>Examiner</b> James D. Anderson	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-51 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11, drawn to methods of treating cancer with a dithiocarbamate thiolate anion of the formula IIB, classified in class 514, subclass 499.
- II. Claims 12-31, drawn to methods of reducing hypoxic or ischemic damage to the cardiovascular system with a dithiocarbamate thiolate anion of formula IIB or of the formula recited in Claim 22, classified in class 514, subclass 499.
- III. Claims 32-51, drawn to methods of treating asthma or arthritis with a dithiocarbamate thiolate anion of formula IIB or of the formula recited in Claim 42, classified in class 514, subclass 499.

The inventions are distinct, each from the other because of the following reasons:

Groups I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions of Groups I and II are drawn to methods of treating cancer and reducing hypoxic or ischemic damage to the cardiovascular system, respectively. The inventions are unrelated because they have different modes of operation and effect and are not capable of being used together. The distinct inventions have different modes of operation and different patient populations. Although both inventions use the same class of compounds, namely dithiocarbamate thiolate anions, the method of treating

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cancer with said compounds (Group I) is not related to the method of reducing hypoxic or ischemic damage to the cardiovascular system (Group II). For example, chemotherapeutics traditionally used to treat cancer would not be considered useful in reducing hypoxic or ischemic damage to the cardiovascular system and *vice versa*.

Groups I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions of Groups I and III are drawn to methods of treating cancer and asthma or arthritis, respectively. The inventions are unrelated because they have different modes of operation and effect and are not capable of being used together. The distinct inventions have different modes of operation and different patient populations. Although both inventions use the same class of compounds, namely dithiocarbamate thiolate anions, the method of treating cancer with said compounds (Group I) is not related to the method of treating asthma or arthritis (Group III). For example, chemotherapeutics traditionally used to treat cancer would not generally be considered useful in treating asthma or arthritis and *vice versa*.

Groups II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions of Groups II and III are drawn to methods of treating cancer and reducing hypoxic or ischemic damage to the cardiovascular system, respectively. The inventions are unrelated because they have different modes of operation and effect and

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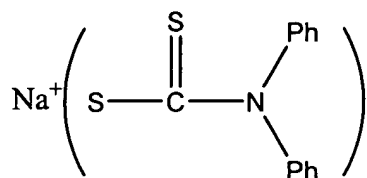
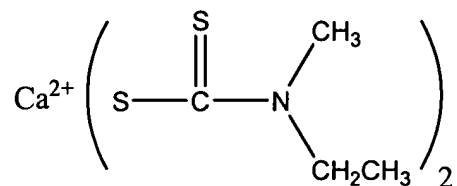
are not capable of being used together. The distinct inventions have different modes of operation and different patient populations. Although both inventions use the same class of compounds, namely dithiocarbamate thiolate anions, the method of reducing hypoxic or ischemic damage to the cardiovascular system (Group II) is not related to the method of treating asthma or arthritis (Group III). For example, compounds traditionally used cardioprotective agents would not generally be considered useful in treating asthma or arthritis and *vice versa*.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

***Election of Species Requirement for Either of Groups I or II or III***

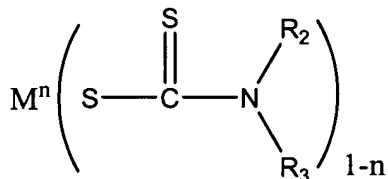
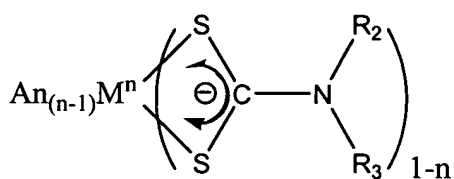
Claims 1-51 are generic to the following disclosed patentably distinct species: the multitude of compounds encompassed by the dithiocarbamate thiolate anions represented by general Formula IIB (Claims 1, 12, and 32) and the dithiocarbamate thiolate anions represented by the formula recited in Claims 22 and 42. The species are independent or distinct because to search all of the compounds encompassed by the recited formulas would present an undue search burden on the Examiner. For example, compounds of formula IIB would encompass the following distinct structures:

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**A****B**

A search for Compound A would not result in identification of Compound B and *vice versa*. Because of the multitude of possible combinations of metals, R<sub>2</sub>, and R<sub>3</sub> groups, election of a single disclosed species is required for examination purposes. The same rational is true for the dithiocarbamate thiolate anions represented by the formula recited in Claims 22 and 42. To search the multitude of possible combinations of metals (An), alkali metals (M), R<sub>2</sub>, and R<sub>3</sub> groups encompassed by the general formula recited in Claims 22 and 42 would present an undue search burden on the Examiner.

Thus, in addition to the Restriction Requirement, Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species of Formula IIB and a single disclosed species of the formula recited in Claims 22 and 42, even though this requirement is traversed. If Applicant elects Group I, only a specific compound of Formula IIB needs to be selected.

**IIB****Formula of Claims 22 and 42**

Applicant is required to elect ONE species of Formula IIB by identifying a specific metal (M), R<sub>2</sub> and R<sub>3</sub> substituent. Applicant is further required to elect ONE species of

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the formula recited in Claims 22 and 42 by identifying a specific alkali metal (M), R<sub>2</sub>, R<sub>3</sub>, and metal represented by An if Group II or Group III is elected.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

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Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

### ***Conclusion***

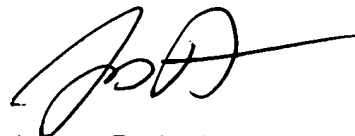
Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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James D. Anderson  
Examiner  
Art Unit 1614

JDA  
May 4, 2006



**ARDIN H. MARSCHEL**  
**SUPERVISORY PATENT EXAMINER**